

§ 524.1580

(3) *Limitations.* Tetracaine and neomycin have the potential to sensitize. If signs of irritation or sensitivity develop, discontinue use. Prolonged use of this product may result in overgrowth of nonsusceptible organisms. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 5265, Feb. 4, 1983; 48 FR 8055, Feb. 25, 1983]

§ 524.1580 Nitrofurazone ophthalmic and topical dosage forms.

§ 524.1580a [Reserved]

§ 524.1580b Nitrofurazone ointment.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsor.* For use on dogs, cats, or horses, see Nos. 000010, 000857, 000864, 000069, 050749, 023851, 051259, and 061133 in § 510.600(c) of this chapter. For use on dogs and horses, see No. 017135 in § 510.600(c) of this chapter. For use on horses, see No. 017153 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.¹

(2) *Limitations.* Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.¹

[46 FR 43402, June 27, 1980, as amended at 49 FR 6476, Feb. 22, 1984; 50 FR 49373, Dec. 2, 1985; 52 FR 18691, May 19, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 29544, July 13, 1989; 54 FR 37097, Sept. 7, 1989; 55 FR 8462, Mar. 8, 1990; 55 FR 20455, May 17, 1990; 56 FR 37473, Aug. 7, 1991; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997; 66 FR 14074, Mar. 9, 2001]

21 CFR Ch. I (4–1–02 Edition)

§ 524.1580c Nitrofurazone soluble powder.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsor.* See Nos. 000010, 000069, and 050749 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply several times daily to the lesion or affected area from the plastic squeeze bottle.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, skin ulcers, and abscesses after incision.¹

(3) *Limitations.* In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian. For use only on dogs, cats, and horses (not for food use).¹

[45 FR 43402, June 27, 1980, as amended at 47 FR 43368, Oct. 1, 1982; 48 FR 28984, June 24, 1983; 53 FR 40728, Oct. 18, 1988; 54 FR 30542, July 21, 1989; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997]

§ 524.1580d [Reserved]

§ 524.1580e Nitrofurazone ointment with butacaine sulfate.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone and 0.5 percent butacaine sulfate in a water-soluble base.

(b) *Sponsor.* See No. 051259 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For prevention or treatment of surface bacterial infections of ears, wounds, burns, and cutaneous ulcers of dogs, cats, and horses.¹

(2) *Limitations.* Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

Food and Drug Administration, HHS

§ 524.1600b

deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.¹

[49 FR 9417, Mar. 13, 1984]

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thioestrepton, and triamcinolone acetone ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thioestrepton; and 1.0 milligram of triamcinolone acetone.

(b) *Sponsors.* For petrolatum base ointments see 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter. For vanishing cream base ointments see 051259 and 053501.

(c) *Conditions of use*—(1) *Amount.* (i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.

(2) *Indications for use.* (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections.

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.

(3) *Limitations.* For mild inflammations, use once daily to once a week.

For severe conditions, apply initially two to three times daily, decreasing frequency as improvement occurs. Not intended for treatment of deep abscesses or deep-seated infections. Not for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 29770, July 11, 1978; 50 FR 41490, Oct. 11, 1985; 53 FR 39257, Oct. 6, 1988; 54 FR 5431, Feb. 3, 1989; 54 FR 48090, Nov. 21, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 61 FR 63712, Dec. 2, 1996; 64 FR 42831, Aug. 6, 1999]

§ 524.1600b Nystatin, neomycin, thioestrepton, and triamcinolone acetone ophthalmic ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thioestrepton, and 1.0 milligram of triamcinolone acetone.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for ophthalmic use as an anti-inflammatory, antipruritic, antifungal (*Candida albicans*), and antibacterial ointment for local therapy in keratitis and conjunctivitis in cats and dogs and for infectious keratoconjunctivitis (pink eye) in cattle.

(2) It is to be administered as follows:

(i) For conjunctivitis and keratitis: Apply one drop of ointment to the affected eye(s) two or three times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) For bovine infectious keratoconjunctivitis: Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iii) Frequency of administration is dependent on the severity of the condition. For mild inflammations, applications may range from once daily to once a week; for severe conditions the drug may be applied as often as two to three times daily. Frequency of treatment may be decreased as improvement occurs.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]